

K110849

APR 26 2011

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name

Proprietary Device Name: PrestoDR 4143

Establishment Name and Registration Number of Submitter

Name: CMT Medical Technologies Ltd.

Registration: 8030112

Submission contact: Shlomi Dines

Hacarmel St. Bld 7/2, POB. 111,

Industrial Park, Yoqneam Ilit 20692, ISRAEL,

Tel:+972-4-8566220 +972-52-4854411, Fax:+972-3-5212202,

Device Classification

Product Code: MQB

Regulation Number: 892.1650

Common Name: Solid state X-Ray imager

Classification Name: Image intensified fluoroscopic x-ray system

Regulatory class: Class II

Reason for 510(k) Submission

Special 510(k) Submission

Identification of Legally Marketed Equivalent Devices

K100400 PrestoDR 4143

Device Description

The PrestoDR 4143 is a Digital Radiography system, featuring an integrated flat panel digital detector (FPD) and CMT's proprietary technology, which incorporates state of the art object-oriented software and connectivity. The legally marketed PrestoDR Portable K100400 has been modified: To integrate the Pixium 4143 flat panel digital detector (FPD), improve its cost effectiveness, aging technologies and components (hardware and software) have been redesigned. The device major functions, intended use and principle of operation were not changed.

Indications for use

The PrestoDR 4143, is intended for use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. PrestoDR 4143 allows imaging of the skull, chest, shoulders, spine, abdomen, and extremities.

Safety & Effectiveness

The device has been designed verified and validated complying with 21CFR 820.30 regulations. Tests data demonstrate that the PrestoDR 4143 meets the required specifications. No adverse affects have been detected.

Substantial Equivalency

It is CMT opinion that the PrestoDR 4143 is substantially equivalent in terms of safety and effectiveness to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Shlomi Dines
Director of Quality and Regulatory Affairs
CMT Medical Technologies, Ltd.
Hacanean St. 7/2, PO Box 111 Industrial Park
YORKNEAM ILIT 20692
ISREAL

AUG 20 2013

Re: K110849
Trade/Device Name: PrestoDR 4143
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray System
Regulatory Class: II
Product Code: KPR
Dated: March 1, 2011
Received: March 28, 2011

Dear Ms. Dines:

This letter corrects our substantially equivalent letter of April 26, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

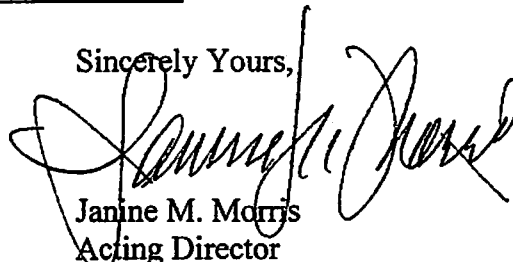
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K110849

Device Name: PrestoDR 4143

Indications For Use: The PrestoDR 4143 TM, is intended for use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. PrestoDR 4143 TM allows imaging of the skull, chest, shoulders, spine, abdomen, and extremities.

Prescription Use: YES
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use: NO
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Pahl

Page 1 of ____

[Signature]
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K110849